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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,508	03/26/2004	Xing Cheng	26-003820US	8613

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EXAMINER	
CHEN, STACY BROWN	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/811,508	CHENG ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,6,10-12,14-16,19,20,27,35,39,46-48,53,60 and 66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,2,4,6,10-12,14-16,19,20,27,35,39,46-48,53,60 and 66* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.C. O

DETAILED ACTION

1. Applicant's preliminary amendment filed July 6, 2004 is acknowledged and entered. Claims 1, 2, 4, 6, 10-12, 14-16, 19, 20, 27, 35, 39, 46-48, 53, 60 and 66 are pending and subject to the following restriction requirement.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 4, 6, 10-12, 14-16, 19, 20 and 27, drawn to a polynucleotides, classified in class 536, subclass 23.1.

- All claims will be examined with respect to SEQ ID NO: 1. However, further restriction is required in Group I between subsequences and polypeptides. Applicant must elect one polynucleotides sequence and one polypeptides sequence that correspond to each other. For example, Applicant elects subsequence SEQ ID NO: 14, and the encoded polypeptides SEQ ID NO: 2.
- With regard to claims 12, 14-16, 19 and 20 are drawn to polypeptides SEQ ID NO: 10 and 12. Applicant must elect a deletion from either SEQ ID NO: 10, or 12.

In summary, Applicant must elect one polynucleotides sequence from claim 1, the corresponding polypeptides sequence from claim 1, and one deleted ORF (SEQ ID NO: 10 or 12).

II. Claims 35 and 39, drawn to a recombinant virus, classified in class 424, subclass 184.1.

- All claims will be examined with respect to SEQ ID NO: 1. However, further restriction is required in Group I between subsequences and polypeptides. Applicant must elect one polynucleotides sequence and one polypeptides sequence that correspond to each other. For example, Applicant elects subsequence SEQ ID NO: 14, and the encoded polypeptides SEQ ID NO: 2.

III. Claims 46, 47, 48, 53, 60 and 66, drawn to a polypeptides, classified in class 424, subclass 184.1.

- Further restriction is required in Group III. Applicant must elect one polypeptides sequence of SEQ ID NO: 2-11 and the polypeptides sequence encoded by SEQ ID NO: 1. Additionally, Applicant must elect one sequence from claim 46(e) if the polypeptides encoded by SEQ ID NO: 1 is elected: SEQ ID NO: 13 or 14.

The inventions are distinct, each from the other because of the following reasons:

a) Restriction between sequences is required because a search for each sequence would be a serious burden on the Office resources. Each sequence is different with regard to amino acid or nucleic acid content and length. Searching one sequence requires comparing the sequence to every sequence in the databases at the PTO. This would be a serious burden on Office resources.

b) The polynucleotides of Group I and the viruses of Group II are patentably distinct inventions. Polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules from viruses, which are complex structures comprised of multiple proteins in

various spatial arrangements. A search of the literature may reveal papers relating to viruses, but not the polynucleotides or their various mutants. Therefore, it would be a serious burden to search both the viruses and the polynucleotides.

c) The polypeptides of Group III and the viruses of Group II are patentably distinct inventions. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules from viruses, which are complex structures comprised of multiple proteins in various spatial arrangements. The viruses of Group II are comprised of more than the polypeptides of Group III. A search of the literature may reveal papers relating to the viruses, but not the particular polypeptides. Therefore, it would be a serious burden to search both the viruses and the polypeptides.

d) The polypeptides of Group III and polynucleotides of Group I are patentably distinct inventions for the following reasons: Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptides. In the present claims, the polynucleotides of Group I do not necessarily encode polypeptides of Group II because the claims include sequences complementary to the coding sequences, and therefore would not encode the polypeptides of Group III. Furthermore, the information provided by the polynucleotides of Group I can be used to make materially different polypeptides than that of Group III. For these reasons, the inventions of Groups I and III are patentably distinct.

Furthermore, searching the inventions of Groups I and III together would impose a

serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I and III have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotides. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptides but spoke to the gene. Searching, therefore is not coextensive. In addition, the polynucleotide claims include polynucleotides having less than 100% identity to the sequence identified. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. The scope of polynucleotides as claimed extend beyond the polynucleotides that encodes the claimed polypeptides as explained above. As such, it would be burdensome to search the inventions of Groups I and III together.

Because these inventions are distinct for the reasons given above and the literature/sequence search required for one Group is not co-extensive with any other Group, and therefore a serious burden, restriction for examination purposes as indicated is proper. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product

claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

4. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Stacy B. Chen
August 23, 2005